

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Box 1450 Alexandra, Virginia 22313-1450 www.unpto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,821	07/22/2003	Satoshi Mori	55022DIV (71526)	7795
21874 7599 120862998 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER	
			KUMAR, VINOD	
			ART UNIT	PAPER NUMBER
			1638	•
			MAIL DATE	DELIVERY MODE
			12/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/625,821 MORI ET AL. Office Action Summary Examiner Art Unit VINOD KUMAR 1638 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 05 September 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.2.4.5 and 8-17 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1,2,4,5 and 8-17 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 07 February 2008 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. 09/646,825. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. __ Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date ______.

Notice of Informal Patent Application

6) Other:

Application/Control Number: 10/625,821 Page 2

Art Unit: 1638

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 5, 2008 has been entered.

Status of objections and rejections

- Claims 1-2, 4-5, 8-16 and newly added claim 17 are pending. Claims 3 and 6-7 have been previously canceled.
- Objections to claims 9 and 16 have been withdrawn in light of claim amendments filed in the paper of September 5, 2008.
- The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- Rejection of claim 2 under 35 U.S.C. 112, 2nd paragraph has been withdrawn in light of claim amendment filed in the paper of September 5, 2008.

Claim Objections

6. Claims 1, 4, 8 and 15 are objected to because of the following informalities:

Art Unit: 1638

Claim 1 is objected for reciting "in the plant in the transformed plant" in lines 1-2 of part 4). The phrase does not read properly. It is suggested to delete "in the plant".

Claim 1 is objected for reciting improper article before "modified" in lines 2 and 3 of part 4).

In claim 1, parts "1)", "2)", "3)" and "4)", it is suggested to replace these parts by roman numerals.

Claim 4 is objected for having improper article before "GT" in line 2. It is suggested to change "a" to --the--. It is noted that claim 5 was erroneously objected in the last office action. Objection to claim 4 was also necessitated due to claim amendment filed in the paper of February 7, 2008.

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The method of claim 1 encompasses the polyadenylation signal sequence of ATTTA. Claim 8 indicates that the method does not require the polyadenylation sequence of ATTTA. Claim 8 fails the infringement test because claim 1 would conceivably be infringed by a polyadenylation sequence of ATTTA which would not infringe claim 8. See MPEP § 608.01(n). It may be noted that the recitation "modifying" in part 2) of claim 1 does not necessarily imply that ATTTA sequence is changed.

Claim 15 is objected for having "-" between "to" and "claim" in line 2.

Appropriate action/corrections are required.

Page 4

Art Unit: 1638

Application/Control Number: 10/625.821

Claim Rejections - 35 USC § 112

7. Claims 1-2, 4-5 and 8-16 remain, and newly added claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified yeast FRE1 coding sequence as defined in SEQ ID NO: 1, a transgenic plant and a method of producing said transgenic plant comprising introducing and expressing said coding sequence in said transgenic plant, does not reasonably provide enablement for the scope of possible gene sequences from any species claimed for use in plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons of record stated in the Office action mailed May 7, 2008. Applicant traverses the rejection in the paper filed September 5, 2008.

Applicant argues that the specification cites other genes that may require modification of the coding sequence using the instantly claimed method. Applicant argues that 0014-0016 paragraphs of the specification teaches that Cry gene from *Bacillus thuringiensis* can be modified using instantly claimed method for producing insect resistant transgenic plants (response, pg 6, 5th paragraph through pg 7, last paragraph). Without providing any reasons, Applicant further argues that Grec et al. teachings are not relevant to the issues of enablement raised by the Office. Applicant also argues that PDR5 and MIP of Grec et al. are not heterologous nucleic acid sequences. Applicant continues to argue that examples of transgenic tobacco plants expressing the modified introduced genes are provided in the specification, and thus one skilled in the art would be able to practice the claimed invention to its full scope.

Art Unit: 1638

Applicant further argues the present invention is applicable to any heterologous nucleic acid because since transcription and addition of poly (A) proceed independently from what is encoded in the heterologous nucleic acid (response, pg 8 through 2nd paragraph of pg 10). Applicant further argues that the claimed method relies on mutation of the coding sequence at specific sites, particularly putative polyadenylation signals of ATs and GT rich regions, and thus not necessarily result in the alteration of protein function (response, pg 11, 3rd paragraph). Applicant further argues that practicing the claimed method for its full-scope would not require undue experimentation and cites in re Wands to support the argument (response, pgs 11-12).

Applicant's arguments have been carefully considered but are deemed to be unpersuasive.

It is maintained that claim 1 is directed to a heterologous nucleic acid sequence from any species (plant or non-plant) that can be modified in a region relating to the poly (A) addition of an mRNA of a plant, and wherein said modification comprises changing the base sequence to a sequence which is not related to the poly (A) addition of the mRNA of said plant.

It is maintained that the specification as filed does not provide any other example genes which would require such modification other that the yeast FRE1 gene for expression in tobacco.

It is maintained that plant polyadenylation signals do not have a strict consensus requirement. See for example, Grec et al. (Gene 242, 87-95, 2000) who teach cryptic polyadenylation sites within the coding sequences of PDR5 (pleiotropic drug resistance)

Art Unit: 1638

and MIP (mitochondrial DNA polymerase) genes expressed in tobacco. No AATAAA related elements were found upstream of the cryptic poly A sites of PDR5 or MIP genes expressed in tobacco. However, the instantly claimed method requires identifying said elements in a heterologous sequence.

It is further maintained that other than a vague teaching to look for GT-rich areas in any such gene, and change the sequence to remove certain sequences, one of skill in the art would not immediately envision on what is otherwise any possible heterologous nucleic acid gene sequence as broadly claimed.

It is further maintained that the state of art (see e.g. Grec et al.) indicates that the structure of heterologous nucleic acid sequences, i.e. any gene for instance, is empirically determined and the structural elements of a gene in one species will have different regulatory sequences and different structural elements. Thus there would be an expectation of substantial variation among species encompassed within the scope of the claims because the location of the claimed regions is not readily known absent empirical testing upon use in a plant. It is, therefore, maintained that the specific modifications to the yeast FRE1 gene taught in the specification and claimed as instant SEQ ID NO: 1 do not provide a substantial correlation to any such modification needed or required in any other heterologous nucleic acid sequence broadly claimed.

It is further maintained that claim 1 recites identifying GT rich sequences having 8 or more consecutive G and/or T nucleotides in the heterologous nucleic acid sequence. The specification does not define GT rich region. The GT rich regions identified in figure 4 do not have at 8 G, 8 T or 8 GT consecutive residues. The

Art Unit: 1638

specification does not describe heterologous nucleic acids having GT rich region(s) and comprising 8 G, 8 T or 8 GT consecutive residues.

It is therefore, maintained that other than a vague teaching to look for GT-rich (not defined, emphasis added) areas in any such heterologous nucleic acid, and change the sequence to remove certain sequences, one of skill in the art would not immediately envision on what is otherwise any possible heterologous nucleic acid sequence as broadly claimed.

In the absence of adequate guidance, it is maintained that undue experimentation would have been required by a skilled artisan at the time the claimed invention was made to determine how to modify the polyadenylation and GT rich sequence in said heterologous nucleic acid sequence such that the modified heterologous nucleic acid sequence expresses and produces the functional protein in a transformed plant.

It is, therefore, maintained that the claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim

Art Unit: 1638

It is, therefore, maintained that given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention commensurate in scope with the claims.

8. Claims 1-2, 4-5, and 8-16 remain and newly added claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed May 7, 2008.
Applicant traverses the rejection in the paper filed September 5, 2008.

Applicant traverses the rejection in the paper filed September 5, 2008.

Applicant continues to argue that claims have been amended to recite specific polyadenylation signal sequences, and the specification clearly describes factors that are required in a genus of nucleic acid sequences comprising a coding sequence which has been modified to encode a functionally unaltered protein. Applicant further argues that the specification provides a number of genes for use in the method of invention. Applicant continues to argue that those skilled in the art would recognize that Applicant was in possession of the claimed invention at the time of filing (response, pg 13).

Applicant's arguments have been carefully considered but are deemed to be unpersuasive.

Art Unit: 1638

It is maintained that the essential feature of claim 1 is a heterologous nucleic acid sequence from any organism (plant or non-plant species), comprising a polyadenylation signal sequence and a GT rich sequence as instantly claimed.

The specification as filed describes modifications of the yeast FRE1, as set forth in SEQ ID NO: 1, for use in plants. The specification describes transgenic tobacco plants expressing modified yeast FRE1. The transgenic plants expressing modified yeast FRE1 exhibited functional enzymatic activity. See Figures 1-18; pages 22-37, examples 1-9.

The breadth of claim 1 encompasses sequences having a polyadenylation signal sequence and a GT rich sequence, wherein the GT rich sequence is 8 or more consecutive G and/or T residues.

It is maintained that the specification as filed does not provide any other example genes which would require such modification other that the yeast FRE1 gene for expression in tobacco. There would be an expectation of substantial variation among species encompassed within the scope of the claims because the location of the claimed regions is not readily known absent empirical testing upon use in a plant. The specific modifications to the yeast FRE1 gene taught in the specification and claimed as instant SEQ ID NO: 1 do not provide a substantial correlation to any such modification needed or required in any other nucleic acid sequence broadly claimed. One of skill in the art would conclude that Applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claims.

Art Unit: 1638

Accordingly, it is maintained that there is lack of adequate description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed.

Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Also see in re Curtis (69 USPQ2d 1274 (Fed. Cir.2004), where the court held that there was sufficient evidence to indicate that one of ordinary skill in the art could not predict the operability of other species other that the single one disclosed in the specification. The court held that a disclosure naming a single species can support a claim to a genus that includes that species if a person of ordinary skill in the art, reading the initial disclosure, would "instantly recall" additional species of the genus already "stored" in the minds, but if other members of the genus would not "naturally occur" to a person of ordinary skill upon reading the disclosure, then unpredictability in performance of species other than specifically enumerated defeats claims to the genus.

For at least these reasons and the reasons of record stated in the previous Office Action, the requirement for written description has not been met. Accordingly, the rejection is maintained.

Claims 1-2, 4-5, and 8-16 remain and newly added claim 17 is rejected under 35
 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Art Unit: 1638

The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed May 7, 2008.

It is maintained that claim 1 recites "8 or more consecutive G and/or T nucleotides" which introduces **NEW MATTER** into amended claim. The specification does not provide written description support for *8 or more consecutive G and/or T nucleotides".

Applicant traverses the rejection by arguing that paragraph 0134 of the specification describes the phrase "8 or more consecutive G and/or T nucleotides". It is noted that the paragraph 0134 of the specification states "consisting of continued base sequence of 8 bases or more without containing sequence consisting of only G or T". The specification fails to provide support for the full scope of instantly claimed phrase "8 or more consecutive G and/or T nucleotides". Thus, such a phrase constitutes **NEW MATTER**. In response to this rejection, Applicant is required to point to support for the phrase "8 or more consecutive G and/or T nucleotides" or to cancel the new matter.

Dependent claims 2, 4-5, 8-16 and newly added claim 17 are also rejected because they fail to overcome this deficiency.

Claim 9 recite "ACCATGG" which introduces **NEW MATTER** into amended claims. The specification does not provide written description support for the sequence "ACCATGG". This does not comply with written description requirements.

It was suggested to the Applicant (claim objection, pg 3, Office Action May 7,

Art Unit: 1638

2008) to insert --ACCATGG-- provided Applicant can provide support for the sequence in the specification. Since the specification does not provide the written description support for the sequence "ACCATGG", it therefore, constitutes **NEW MATTER** into the amended claim.

Claim Rejections - 35 USC § 103

10. Claims 1, 4-5, 8 and 14-16 remain, and newly added claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perlak et al. (PNAS, 88:3324-3328, April 1991, Applicant's IDS), and further in view of Joshi (Nucleic Acids Research, 15:9627-9640, 1987) for the reasons of record stated in the Office action mailed May 7, 2008.

Applicant traverses the rejection in the paper filed September 5, 2008.

Applicant argues that Perlak et al. do not teach that GT rich sequences could be a polyadenylation signal in a combination with ATs (response, pg 15, lines 19-22). Applicant also argues that Joshi only teaches 5 consecutive G and/or T residues, not 8 as required by claims (response pg 15, lines 24-28). Applicant further argues that it would not be obvious that the combination of GT rich sequences and ATs could be a polyadenylation signals at the time the claimed invention was made (response, pg 16, lines 3-17).

Applicant's arguments have been carefully considered but are deemed to be unpersuasive.

It is maintained that Perlak et al. teach a method of making a transgenic plant and seeds derived thereof, comprising introducing and expressing a modified coding

Art Unit: 1638

sequence *cryIA(b)* gene of *Bacillus thuringiensis* in transgenic tobacco and tomato plants. The transgenic plants exhibited improved insect resistance. The modification did not alter the amino acid sequence of the CryIA(b) protein. The modification of coding sequence for *cryIA(b)* comprised altering AATAAA and/or ATTTA sequences. Furthermore, the modification increased G and C content throughout the region of gene to be introduced, and modification was based on plant preferred codons without changing the amino acid sequence. See in particular, page 3324, abstract; page 3324, 2nd paragraph, materials and methods (modification of the coding sequence of insect control genes) through the end of 2nd paragraph of 1st column of page 3325; page 3325, Table 1; page 3326, Figure 1, Table 2; page 3327, Figure 2, Table 3; Page 3328, 1st column, discussion.

It is further maintained that Joshi teaches plant gene sequences having GT-rich sequences resembling animal GT-rich sequences found downstream of polyA sites. Joshi also teaches that deletion analysis in the 3' untranslated region of plant mRNA transcripts reveals a region 30 to 80 bases downstream AATAAA comprises GT rich motifs that are also required for correct and efficient polyadenylation of plant mRNA transcripts. See in particular, page 9627, abstract; page 9628, lines 16-31; pgs 9629-9631, table 1.

It is maintained that it would have been obvious and within the scope of an ordinary skill in the art to modify the method of altering heterologous nucleic acid sequence as taught by Perlak et al. by modifying internal plant polyadenylation signals that comprises AATAAA and/or ATTTA and GT rich regions as taught by Joshi.

Art Unit: 1638

Given that Joshi et al. teach that plant GT rich regions are associated with polydenylation process in plants, one of ordinary skill in the art would have been motivated to modify GT rich regions in said heterologous sequence to prevent premature termination of transcription with a reasonable expectation of success.

Given that Joshi clearly asserts the importance of GT rich regions in the polyadenylation of plant mRNA transcripts, it would have been obvious that any GT rich region including the one having 8 or more consecutive G or T and/or nucleotides would have been scanned and subsequently modified by an ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have arrived at the claimed invention by combining the teachings of Perlak et al. and Joshi with a reasonable expectation of success.

In response to Applicant's argument that Joshi does not teach 8 or more consecutive G and/or T nucleotides, Applicant is reminded that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly

Art Unit: 1638

suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, based on the fact GT-rich regions in combination with ATs were implicated in polyadenylation at the time the invention was claimed, it would have been obvious to modify heterologous sequences having internal ATs and GT-rich regions to prevent premature termination of the transcript when expressed in a plant with a reasonable expectation of success.

Thus, it is maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Claim 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over
 Perlak et al. (PNAS, 88:3324-3328, April 1991) in view of Joshi (Nucleic Acids
 Research, 15:9627-9640, 1987) and Kozak (Nucleic Acids Research, 9:5233-5252,
 1981) for the reasons of record stated in the Office action mailed May 5, 2008.

Applicant traverses the rejection by making same arguments as discussed above.

Accordingly, the rejection is maintained.

 Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perlak et al. (PNAS, 88:3324-3328, April 1991) in view of Joshi (Nucleic Acids Research, 15:9627-9640, 1987), and further in view of Dancis et al. (PNAS, 89:3869-3873, Published May 1992).

Perlak et al. teachings are discussed supra.

Art Unit: 1638

Joshi teachings are discussed supra.

Perlak et al. or Joshi do not teach FRE1 from yeast.

Dancis et al. teach a nucleic acid sequence which is heterologous to plant, and encoding yeast ferric-chelate reductase FRE1 (a protein involved in absorption of iron, a plant nutrient). The nucleic acid sequence taught in the reference comprises internal ATs and GTs which would be recognized as polyadenylation signals in plants. See in particular, pg 3869, abstract; pg 870, figure 1; pg 3873 discussion.

It would have been obvious and within the scope of an ordinary skill in the art to modify the method of altering any heterologous nucleic acid sequence as taught by Perlak et al. by modifying internal plant polyadenylation signals that comprises AATAAA and/or ATTTA and GT rich regions as taught by Joshi.

Given that Joshi et al. teach that plant GT rich regions are associated with polyadenylation process in plants, one of ordinary skill in the art would have been motivated to modify GT rich regions in said heterologous sequence to prevent premature termination of transcription with a reasonable expectation of success.

Given that Joshi clearly asserts the importance of GT rich regions in the polyadenylation of plant mRNA transcripts, it would have been obvious that any GT rich region including the one having 8 or more consecutive G or T and/or nucleotides would have been scanned and subsequently modified by an ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success.

Given that Dancis et al. teach a heterologus sequence from yeast encoding FRE1 which is involved in the absorption of nutrients, it would have been obvious and within the scope of an ordinary skill in the art to modify internal ATs and GT-rich regions of Dancis et al. FRE1 coding sequence using the teachings of Perlak et al. and Joshi as discussed above, for the purpose of over-expressing full-length FRE1 protein to increase absorption of iron (a nutrient) in transgenic plants with a reasonable expectation of success.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perlak et al. (PNAS, 88:3324-3328, April 1991) in view of Joshi (Nucleic Acids Research, 15:9627-9640, 1987), and further in view of D'Halluin et al. (Plant Cell, 4:1495-1505, December 1992).

Perlak et al. teachings are discussed supra.

Joshi teachings are discussed supra.

Perlak et al. or Joshi do not teach transforming a monocotyledonous plant.

D'Halluin et al. teach a method of transforming maize plant. Maize is a monocotyledonous plant. See in particular, pg 1495, abstract; pgs 1503-1504, materials and methods.

It would have been obvious and within the scope of an ordinary skill in the art to over-express a heterologous DNA (modified by removing internal ATs and GT rich regions as taught by Perlak et al. and Joshi) encoding an economically important protein, in any plant species including an economically important maize plant using the plant transformation method of D'Halluin et al. One of ordinary skill in the art would have been motivated to do so for the purpose of genetically improving a monocotyledonous plant, such as maize plant.

Application/Control Number: 10/625,821 Page 18

Art Unit: 1638

Conclusions

14. Claims 1-2, 4-5, and 8-16 remain, and newly added claim 17 is rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VINOD KUMAR whose telephone number is (571)272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vinod Kumar/

Examiner, Art Unit 1638